Remarks

Claims 1-9 were pending in the subject application. By this Amendment, claims 1 and 4 have been amended, claims 2, 4, 5, and 9 have been cancelled, and new claim 10 has been added. The undersigned avers that no new matter is introduced by this amendment. Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 1, 3, 6-8 and 10 are currently before the Examiner for consideration. Favorable consideration of the pending claims is respectfully requested.

Initially, as noted in the outstanding Office Action, the applicant has elected TGF-β as the species for examination at this time. The claims have been amended herein, consistent with that election to recite TGF-β. Please note that this election of species and accompanying amendments to the claims render moot the substantive rejections concerning patentability in the outstanding Office Action.

Also, the applicant wishes to express his appreciation for the Examiner's indication of allowable subject matter.

Turning to the specific rejections set forth in the outstanding Office Action, as explained in more detail below, the applicant respectfully submits that the claims now presented are fully enabled and patentable over the cited art.

Claims 1, 2 and 6-9 have been rejected 35 U.S.C. §112, first paragraph. The applicant respectfully submits that the claims as filed were fully enabled and in compliance with the "written description" requirement of 35 U.S.C. §112, first paragraph. However, the applicant's amendment, whereby TFG-β has been recited in conformance with the applicant's election of species, has rendered moot this grounds for rejection.

Claims 1-3, 6 and 9 have been rejected 35 U.S.C. §102(b) as being anticipated by Reder *et al.*, 1994 (*J.* Neuroimmunol. 54:117-127); claims 1-3, and 6-9 have been rejected under 35 U.S.C. §102(b) as being anticipated by by Secchi *et al.*, 1986 *(Transpl. Proceed. XVIII*, 1540-1542); claims 1, 2, 6 and 9 have been rejected under 35 U.S.C. §102(b) as being anticipated by any of Kuruvilla *et al.*, Racke *et al.* or Johns *et al.* (cited on 892) in light of Wahl, 1992 (*J. Clin. Immunol.* 12:61); claims 1, 2, 7 and 9 have been rejected under 35 U.S.C. §102(b) or (e) as being anticipated by Bond *et al.* (WO 94/08606 or U.S. 5,827,513) in light of Howard *et al.*; claims 1, 2 and 9 have been

rejected under 35 U.S.C. §102(a) or (b) as being anticipated by Ducharme *et al.* (U.S. 5,474,995 or WO 95/18799); claims 1, 2, 7 and 9 have been rejected under 35 U.S.C. §102(a) or (b) as being anticipated by Talley *et al.* (U.S. 5,466,823 or WO 95/15316); and claims 1-3, 5 and 9 have been rejected under 35 U.S.C. §102(e) as being anticipated by Young *et al.* (U.S. 6,048,850). The applicant respectfully traverses these grounds for rejection to the extent that they might be applied to the newly-amended claims.

Court decisions clearly establish that rejections under 35 U.S.C. §102 are appropriate only in those instances where a single prior art reference has placed into the public domain the very invention which is clamed. In *Lindemann v. American Hoist and Derrick Co.*, 221 USPQ 481 (Fed. Cir. 1984), the court stated:

> Anticipation requires the presence in a single prior art reference, disclosure of each and every element of the claimed invention, arranged as in the claim. *Connell v. Sears Roebuck and Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983); *SSIH Equip. S.A. v. USITC*, 718 F.2d 365, 216 USPQ 678 (Fed. Cir. 1983). In deciding the issue of anticipation, the [examiner] must identify the elements of the claims, determine their meaning in light of the specification and prosecution history, and identify corresponding elements disclosed in the allegedly anticipating reference. *SSIH, supra*; *Kalman [v. Kimberly-Clarke*, 713 F.2d 760, 218 USPQ 781 (Fed. Cir. 1983)] (emphasis added). 221 USPQ at 485.

In *Dewey & Almy Chem. Co. v. Mimex Co.*, Judge Learned Hand wrote:

> No doctrine of the patent law is better established than that a prior patent . . . to be an anticipation must bear within its four corners adequate directions for the practice [of the subsequent invention] . . . if the earlier disclosure offers no more than a starting point . . . if it does not inform the art without more how to practice the new invention, it has not correspondingly enriched the store of common knowledge, and it is not an anticipation. 124 F.2d 986, 990; 52 USPQ 138 (2nd Cir. 1942).

In the current case, none of the cited references disclose, or suggest, a method for inhibiting the development of an autoimmune disease wherein the method involves the administration of TBF-β to an individual in need of such treatment; and wherein the autoimmune disease is not multiple sclerosis. Accordingly, the applicant respectfully requests reconsideration and withdrawal of the rejections under 35 U.S.C. §102.

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Claims 1 and 6-8 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Lemmark *et al.* (WO 92/20811) in view of Bond *et al.* The applicant believes that this rejection has been rendered moot in view of the presentation of claims limited in accordance with the applicant's election of species.

It should be noted that a finding of obviousness is proper only when the prior art contains a suggestion or teaching of the claimed invention. Here, none of the cited references contains a suggestion to utilize TGF-β as claimed by the current applicant. The mere fact that the purported prior art could have been modified or applied in a manner to yield applicant's invention would not have made the modification or application obvious unless the prior art suggested the desirability of the modification. *In re Gordon*, 221 USPQ 1125, 1127 (Fed. Cir. 1984). Moreover, as expressed by the CAFC, to support a §103 rejection, "[b]oth the suggestion and the expectation of success must be founded in the prior art . . . ." *In re Dow Chemical Co., supra* at 1531. In the current case, none of the references, alone or in combination, suggest the currently-claimed invention.

Claims 1, 2 and 6-9 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,168,792. The applicant is submitting herewith a terminal disclaimer with regard to the '792 patent. In view of the submission of this terminal disclaimer the applicant respectfully submits that the obviousness-type double patenting rejection has been rendered moot.

In view of the foregoing remarks and amendments to the claims, the applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16 or 1.17 as required by this paper to Deposit Account 19-0065.

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The applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,

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Attachments: Terminal Disclaimer